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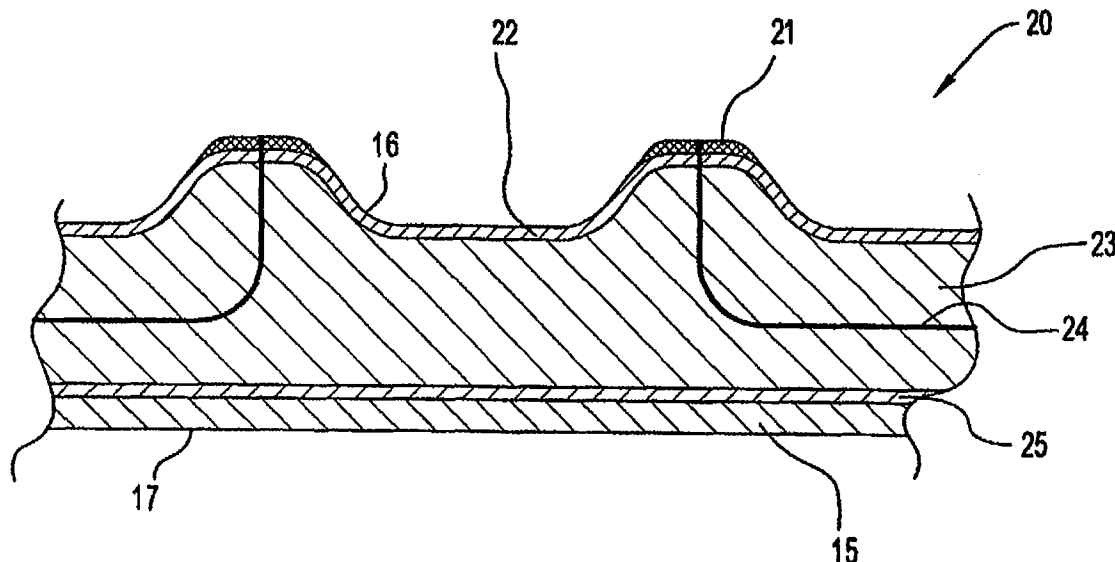
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(54) Title: AN APPARATUS FOR DETECTING, MEASURING AND SELECTING PHYSIOLOGICAL SIGNALS AND A METHOD THEREOF



(57) Abstract: An apparatus for detecting and measuring physiological signals comprising a sensor device with a plurality of electrodes (11, 21, 31) and a signal processing means (90). The sensor device and the signal processing means (90) form an integral unit (10, 20, 30, 80) shaped as a flat element to be engaged with the torso of a human body for measuring the activity of the heart. The integral unit (10, 20, 30, 80), which is easy to handle for a person without medically skill, has selection means (100) for selecting signals according to pre-set conditions and means for transferring the selected signals to a medical skilled person at an external location.

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An apparatus for detecting, measuring and selecting physiological signals and a method thereof.

5 **Technical field**

The present invention relates to an apparatus for detecting and measuring signals comprising a sensor device having a plurality of electrodes isolated from each other to be non-invasively engaged with a torso of a human being,
10 and signal processing means connected to said plurality of electrodes.

The invention also relates to a method for processing physiological signals.

15 **Prior art**

Many people all around the world suffer from different kinds of heart diseases. For example, there is a frequency of 20% for one or more heart diseases among the American population according to the American Heart
20 Association. Taking into account the great number of people who are in the risk zone for getting a heart disease of various reasons, such as hereditary, passiveness, smoking, or bad lifestyle regarding food, drinking and stress, the frequency will rapidly rise.

25 At a heart attack it is very important to get the patient under care as soon as possible since the chance for a successful treatment decreases for every lapsed minute after the heart attack. In addition the care will be less expensive and the recovering period for the patient will be
30 shorter. Another point is to eliminate false alarms at an early stage for avoiding unnecessary resources to be allocated.

The individuals, who have been lucky to stand a first heart attack, live under constant pressure to get another
35 one. The time for postoperative treatment in hospital, for

example after a heart operation, has decreased due to the costs. Both patients and doctors feel that the possibilities for adequate surveillance at home are minimal since no equipment, which is reliable and easy to handle for the patients themselves, is available on the market.

Currently existing equipment for cardiac measurement presumes that the patient must go to a medical centre of any kind to get a relevant diagnose, or that a doctor or an ambulance having relevant equipment and medically skilled personal must visit the patient. Valuable time for both patients and medical personal will be spent on routine controls.

The most common way to get a status of a heart is to provide an electrocardiogram (ECG) for analysing the activity of the heart in combination with another measurement such as a blood sample, the examination being completed with an oral discussion between the doctor and the patient. A conventional 12-channel or 12-lead electrocardiograph is used, where surface potentials then are measured from a limited number of locations, i.e. a maximum of nine points, in relation to a zero potential point according to an established WHO-standard. A detection of ischaemic damage or disease is then provided showing a PQRS-complex, and by studying changes in this graph, for example an elevated ST-wave, pathological defects of the heart may be identified such as a myocardial infarct or an arrhythmia. This is a well-known method requiring medically skilled persons, e. g. a nurse for correctly positioning the electrodes in a pattern according to the standard and for performing the measurements, and a doctor for analysing the results. One disadvantage is however that this method usually has to be performed at a hospital or at another clinical institution; another one is that the doctor could be interested to study another part of the heart, which is impossible using this standard method.

Various parameters are involved in recording an electrocardiogram of acceptable quality for identifying a PQRS-complex showing the activity of a single heartbeat. It is important to get strong signals with sufficient
5 resolution, which depends on correct positioning of the electrodes on the torso of the patient and good contact between electrodes and skin. The electrodes often have to be rearranged since weak signals may be received due to the individual anatomy of the patient. The contact is pro-
10 portional to the conductivity and the normal force from the electrode, which is almost negligible; usually a gel has to be applied on the electrodes to improve the contact between the electrodes and the body. However, the gel smears and may cause irritated skin. Adhesive tape is often used to
15 keep the electrodes in place, which also may cause irritations, and is furthermore not a good solution in combination with a smeary gel.

It is also important to be aware of the fact that faulty or misleading signals may arise from muscular
20 twitching or movement disorder. The electrodes attached to the skin measure the activity of the heart, which is transferred as electrical signals to the ECG-monitor, but are also affected by the muscular twitching from the protective muscles surrounding the heart leading to dis-
25 tortion of the signal. Often this distortion is strong enough to hide important details in the ECG-curve, e.g. the P-wave or the ST-segment. Noise contamination such as DC polarisation and low or high frequency radiation may also affect the signals. Thus, it is desirable to be able to
30 choose the signals having the most favourable relation between signal and distortion, which however requires a medically skilled person to rearrange the electrodes in more advantageous positions.

Movable equipment is available which may be used at
35 emergency, for example in an ambulance; however, a

medically skilled person must operate such equipment. In such situations it is very important to get a rapid indication of the status of the heart. Using normal electrodes would take too long time; instead another type of sensor device may be utilised, for example an array of electrodes which is attached to the torso as a pad. A portable electrocardiograph is disclosed in GB 2 264 176 A comprising an array of 40-100 electrodes each capable of detecting an electrical signal associated with the Q- and/or ST-components of a heartbeat. The array is connected to a microprocessor-controlled interface, which is in communication with an analyser and a display apparatus. Each electrode detects the same ST-wave as generated from different sections of the heart, but depending on the position of the electrode relative to the heart the signals require various amplification. A substantially three-dimensional picture or map of the condition of the heart is represented on a display to be analysed by a doctor.

US-5 819 741 discloses a cardiac monitoring system and a system for advanced ischemia and infarction analysis and monitoring, wherein the system performs calculations on electrocardiograph signals to obtain parameter values related to these diseases. The result of each analysed time interval is presented as points in a trend graph on a monitoring display. The performance and calculations are made on-line and are representing real-time values. A system and a method for monitoring, analysing and diagnosing cardiac activity that display a state of signals received from leads attached to a patient are also provided.

In WO 00/19892 an electrode is shown having a position system for detecting and analysing electrical activity in the anatomy of a human being. This system includes an electrode array and a method for diagnosing muscle activity in the lower lumbar region of human beings,

wherein signals correlated to the underlying anatomy are represented by various output devices, e.g. including variations in coloration or other qualities in correspondence with representations of underlying structures.

5 A medically skilled person must however handle the above mentioned apparatuses and perform the analysis.

Summary of the invention

10 An object of the present invention is to remedy the drawbacks above and to provide an apparatus for detecting, measuring and selecting physiological signals, which is simple to handle for a human being without any medical or technical knowledge, comprising means for transferring the selected signals to a medically skilled person at an
15 external location.

20 A more specific object of the present invention is to provide an apparatus for detecting, measuring and selecting physiological signals comprising a plurality of electrodes for high accuracy and reliability. The apparatus further comprises selective means for evaluating the signals so that misleading or faulty signals are rejected; thereafter, according to pre-set conditions, the signals are transferred to a medically skilled person at an external location where an electrocardiogram according to established standard is provided for analysis. In addition the
25 invention provides a method to be performed with such an apparatus.

30 In order to achieve said objects the invention provides an apparatus comprising a plurality of electrodes isolated from each other, and signal processing means connected to the electrodes forming an integral unit, which has to be non-invasively engaged with the torso of a human being. The integral unit further comprises a microprocessor, a memory with a software and means for
35 transferring the signals to an external location. The

signals detected from the plurality of electrodes are divided into groups, each group comprising several signals. A single signal from each group is selected according pre-set conditions stored in the memory, and could be
5 transferred to a medically skilled person at a distant location where an electrocardiogram according to established standard is provided for analysis.

Further features of the present invention are defined in the dependent claims. Other purposes and advantages of
10 the present invention will appear from the following detailed description, from the attached drawings as well as from the dependent claims.

Brief description of the drawings

15 The invention will be described in more detail below, reference being made to the accompanying drawings, in which

FIG 1 is a schematic front view of a torso of a human body showing the electrode positions for providing an electrocardiogram according to established standard,

20 FIG 2 is a graphical representation of a an ECG from a single heartbeat of a typical normal heart,

FIG 3 is a cross sectional view of an integral unit of a first embodiment according to the invention,

25 FIG 4 is a cross sectional view of an integral unit of a second embodiment according to the invention,

FIG 5 is a cross sectional view of an integral unit of a third embodiment according to the invention,

FIG 6 is a front view showing the integral unit kept engaged with the torso of a human being by manual force
30 from the hand of the human being,

FIG 7 is a schematic front view of the integral unit shown in any of FIGS 3-5, with the plurality of electrodes divided into groups, each group representing a lead according to established standards as shown in FIG 2,

FIG 8 is a perspective view of the integral unit in a partly folded position,

FIG 9 is a block diagram of the main functional parts of the integral unit shown in FIGS 3-8,

5 FIG 10 is a block diagram of the main parts of the processing unit for the selection of signals,

FIG 11 is a flow chart showing a method of signal processing using the integral unit, and

10 FIG 12 is a flow chart illustrating a system for transferring information regarding measured and selected physiologic signals.

Description of the invention

For analysing the status of a heart usually an
15 electrocardiogram is provided by measuring the electrical activity of the heart according to established standard, which is well known per se. Thus, the body of the patient is divided into different leads, and electrodes C1-C6 are positioned to measure the activity within each lead in
20 relation to placed extremity electrodes R, L, N and F, respectively, as shown in FIG 1. An electrocardiogram is then provided, as shown in FIG 2, wherein the activity in different parts of the heart, featured by the P-, T-, U-wave or the QRS-complex or the ST-segment, may be studied
25 to make a decision regarding the condition of the heart.

An apparatus according to the invention is formed as an integral unit 10, 20, 30, 80 comprising a plurality of electrodes 11, 21, 31 isolated from each other and signal processing means 90 in communication with said electrodes
30 11, 21, 31. The integral unit 10, 20, 30, 80 has a first side 16 comprising said plurality of electrodes 11, 21, 31 protruding from said first side 16, as illustrated in different embodiments 10, 20, 30 in FIG 3-5, and a second opposite side 17 comprising the signal processing means 90.

The integral unit 10, 20, 30, 80 forms a flat element to be non-invasively engaged with the left side of the torso of a patient as illustrated in FIG 6, wherein the apparatus is tightly kept to the torso by pressure from the right hand of the patient. Since no gel has to be used due to the good contact of the electrodes 11, 21, 31, the skin irritation problem because of the gel is eliminated. Another advantage obtained without using gel is that the unit readily may be reused.

The integral unit 10, 20, 30, 80 is constructed of several individual layers 12, 13, 14, 15, 22, 23, 25, 32, 34, 35 made of flexible material. A first embodiment of the invention 10, shown in FIG 3, has a first layer 12 made of an insulating material, wherein the electrodes 11 are transversally arranged with one end protruding from the first layer 12 forming said first side 16 of the integral unit 10 and with the other end in communication with a second layer 13. This second layer 13 comprises conductors not shown, or could preferably be made of a polymeric film having printed conductors. A third layer 14 is provided between the second layer 13 and a fourth layer 15 forming said second side 17 of the integral unit 10, 20, 30, 80. The fourth layer 15 comprises a power source 103 and the signal processing means 90, which will be described in detail below.

The electrodes 11 in the preferred embodiment 10 according to FIG 3 is made of a conductive material, such as a silicone elastomer silver contained therein, preferably 8603 from Nolato Silikonteknik or Silastic Q7-4535 from Dow Corning doped with silver (30-80 %), a material which is approved for medical purposes and has excellent elastic and electrical qualities. An alternative electrode material is silicon containing carbon particles for obtaining the conductive property, e.g. Wacker Elastosil R 570/50. The first layer 12 is made of a soft

silicone elastomer, such as Q7-4535 without containing silver or Wacker Elastosil R 401/50. It is very important that this first layer 12 close to the skin has the capability to adjust to the shape of an individual body for good electrical contact at measurement and hence for obtaining the best possible results. A suitable hardness of above mentioned material is about 40-50 shore A. The third layer 14 is arranged to distribute the pressure from the right hand of the patient applied on the fourth layer 15; a material fulfilling this may be chosen e.g. a micro cellular polymeric material. The fourth layer 15 has the task to transfer the pressure from the applied hand to the electrode side 16 of the integral unit 10, 20, 30, 80, and should therefore be made of a stiffer material than the other layers, e.g. a moulded polymer such as ABS. It will also protect the electronic components 90 and the power source 103, and will support the soft electrodes 11, 21, 31. The fourth layer 15 is also employed as a packaging when the integral unit 10, 20, 30, 80 is not in use, as shown in FIG 8, wherein a partly closed position is illustrated. A hinge 81 is provided to make it possible to fold the apparatus. Alternatively several hinges 81 could be provided for this purpose.

In a second embodiment 20 shown in FIG 4, the electrodes 21 are made of a conductive textile material arranged on parts of the first layer 22, these parts protruding with the textile material on the top hence forming said first side 16 of said integral unit 10, 20, 30, 80. Conductors 24 are connected to the electrodes 21 and are arranged to pass through a second layer 23 to be connected to the signal processing means. The electrodes 21 in this second embodiment 20 can be made of for example FLEX from Axelgaard Manufacturing, a commercial available conductive textile material, and are glued to the first layer 22, which can be a sandwich material made of for

example a soft, flexible polyethylene foam, such as Alveo with a density of about 300 kg/m³. The second layer 23, which balance the pressure on the electrodes 21 from the hand on the fourth layer 15, is made of another type of polyethylene foam, e.g. LP14 with a density of about 30 kg/m³. The third layer 25 is made of cellular polyethylene foam with a density of about 40 kg/m³. The sandwich construction comprising the layers 22, 23, 25 may be obtained in a traditional way by heating all three materials at 200°C; thereafter the final desired shape is obtained in a cooled mould. The fourth layer 15 is the same as in the preferred embodiment 10 described above.

In a third embodiment 30 of the invention shown in FIG 5, the electrodes 31 are made of the same conductive polymeric material as the electrodes 11 in the first preferred embodiment 10 and are arranged in a first layer 32 of the same insulating material as in this preferred embodiment 10. The second layer 34 however is a hollow space containing air that is formed by the first layer 32 and a stiffer third layer 35 made of a plastic material, e.g. ABS, and which is equivalent to the fourth layer 15 in embodiment 10 and 20, respectively. Conductors 33 are connected to the electrodes 31, those pass through the second layer 34 to the signal processing means arranged in the stiffer third layer 35, which in this case also may include an air pump, not shown.

The number of electrodes 11, 21, 31, for example 20-100, is essentially greater than normally required, but with a plurality of electrodes 11, 21, 31 it is not critical how the patient positions the integral unit 10, 20, 30, 80 on the torso. The anatomy also differs between patients, so it is an advantage to be independent of an exact placement of electrodes. The main thing is that the apparatus is placed on the left side over the heart.

According to established standard, as shown in FIG 1, there are precordial leads C1-C6 and extremity leads R, L, N and F, which are to be positioned as follows: C1 is located on the fourth intercostal space at the right sternal margin; C2 is located on the fourth intercostal space at the left sternal margin; C3 is located midway between electrode C2 and electrode C4; electrode C4 is located on the fifth intercostal space at the mid-clavicular line; electrode C5 is located on the same level as electrode C4 and on an anterior axillary line; and electrode C6 is located on the same level as electrode C4 and on a mid-axillary line. One electrode is positioned on the right arm (R), one on the left arm (L), one on the right leg (N) and one the left leg (F).

The plurality of electrodes 11, 21, 31 according to the invention are divided into groups E1-E6, ER, EL, EN and EF representing the above mentioned leads for providing an electrocardiogram, wherein each group E1-E6, ER, EL, EN, EF has several electrodes 11, 21, 31 as shown in FIG 7. There is a correlation between the positions of C1-C6, R, L, N and F in FIG 1, and the groups of electrodes E1-E6, ER, EL, EN, EF in FIG 7. Note that the characteristic feature of electrodes arranged in a triangle, which is essential for obtaining differences in electrical potential between different electrodes, appears in both FIG 7 according to the invention and in FIG 1 according to currently used equipment.

The main functional parts of the signal processing means 90, which are arranged in said second side 17 of the integral unit 10, 20, 30, 80, are shown in FIG 9. As mentioned above, the plurality of electrodes 11, 21, 31 arranged in said first side 16 of the integral unit 10, 20, 30, 80 are in communication with the signal processing means 90. Each single electrode 11, 21, 31 measures an individual signal. Input resistors and components for EMC

(electro magnetic capability) 91 are provided for each electrode 11, 21, 31 as well as low-pass filters 92 for eliminating noise contamination such as DC polarisation and for reducing not valuable signals of high frequency, e.g. distortions from surrounding equipment. The filters 92 are combination-filters and are preferably passive. Each signal passes thereafter a pre-amplifier 93 for buffering the individual input signals. The signals pass a lead fail detector 94 controlled by a processing unit 100 for detecting any failure regarding the electrodes 11, 21, 31, e.g. bad electrical contact or malfunction, and thereafter pass a resistor- and switch- array 95 for mixing the signals properly according to pre-set conditions to a correct output by control of a microprocessor in the processing unit 100. The output signals thereafter pass amplifiers 96 and low-pass filters 97 for reducing not valuable signals of high frequency, e.g. distortions from surrounding equipment, one amplifier 96 and one filter 97 being provided for each signal. The analogue output signals pass to multiplexors 98, wherein one or more signals are selected by control of the microprocessor. The selected signals are then transferred to digital format in an analogue/digital-converter (A/D-converter) 99 for further processing in the processing unit 100. The selection of signals according to pre-set conditions to be transmitted is performed in the processing unit 100. This unit 100 is in communication with a generic serial interface 101 that changes the finally obtained data to a determinative format for fast transmittance by a communication media of a communication unit 102, for example by wireless transmission.

The software of the signal processing means 90 comprised in the processing unit 100 in Fig 9 may include inputs and filters 101, multiplexors 102, selection means 103 and a control unit 106, as shown in FIG 10. The control

unit 106 comprises a microprocessor and memories, wherein pre-set conditions are stored, and is connected to the inputs 101. The input signals are read from the A/D-converter 99 and are passed through filters 101. The
5 filtered signals pass to multiplexors 102 and to a selection unit 103, both being controlled by the control unit 106. The control unit 106 controls the input signals and selects the signals to be transmitted by means of the multiplexors 102 in co-operation with the selection means
10 103. The selection will be described in further detail below. For the transmission of selected signals a driver interface 104 is provided for adaptation to an output driver 105, which in turn is adapted to the chosen transferring media.

15 The flow chart in FIG 11 illustrates in different steps the procedure of selecting signals measured by the plurality of electrodes 11, 21, 31. Before a measurement starts it is assumed that the pre-set conditions are stored in the memories in the control unit 106. The measurement is
20 implemented by software stored and executed by the micro-processor. In a first step 110 internal registers, memories etc. are initialised and pre-set conditions are stored. The measurement is started by checking the position of the integral unit 10, 20, 30, 80 in a second step 111 by
25 measuring the signal intensity of each electrode 11, 21, 31 and by studying the variation of the baseline. If the signal intensity is too low for various groups of electrodes 11, 21, 31 and/or the variation of the baseline is high the contact between the electrodes 11, 21, 31 has
30 to be improved. In this case the next step will be 110 again for rearranging the integral unit 10, 20, 30, 80 in a more advantageous position; otherwise a next step will be 113. In the step 113 a detection regarding arrhythmia will be performed by checking the variation in the positions of
35 the heart beats by a standard QRST-detector and if the

variation is too high the next step will once again be step 111; otherwise the procedure will continue by a step 114. In step 114 the signals from electrodes 11, 21, 31 of each group E1-E6, ER, EL, EN, EF each by each and group by group will pass the selection means 90 of the processing unit 100. If the signal values within a group differ from pre-set values this group will be rejected. In a step 115 the number of rejected groups is checked and if less than 4 groups are left the procedure will start again in step 110; otherwise a next step will be 116, wherein the final selection of signals will be performed by comparing the power spectra of the signals after calculation. The procedure will end in a step 117.

The above described selection procedure is based on a plurality of calculations that now will be described in detail below.

From the plurality of electrodes 11, 21, 31 of the integral unit 10, 20, 30, 80 a number of $A \cdot B$ signals E_{ij} are received, where:

$i = 1, \dots, A$ is the number of leads, e.g. $i = 6$,
 $j = 1, \dots, B$ is the number of electrodes of each lead, e.g. $j = 14$,
 x is the rows of the integral unit 10, 20, 30, 80,
and
 y is the columns thereof.

The check of the position of the integral unit 10, 20, 30, 80, i.e. the position of the plurality of electrodes (11, 21, 31), is performed by measuring every electrode signal. Receiving a weak signal or a signal having a strong variation in the baseline indicates that the integral unit (10, 20, 30, 80) has to be rearranged due to a wrong position or bad contact between the electrodes (11, 21, 31) and the body.

The signal intensity S_{ij} and the base-line variation B_{ij} for the signal E_{ij} are defined by the relations:

$$\begin{aligned} S_{ij} &= \max E_{ij} - \min E_{ij} \text{ , and} \\ 5 \quad B_{ij} &= \max E'_{ij} - \min E'_{ij} \\ &\text{where } E'_{ij} \text{ is a low-pass filtered } E_{ij}. \end{aligned}$$

The position of the plurality of electrodes (11, 21, 31) is considered wrong if:

- 10 the mean value of S is lower than a fix pre-set value $T1$ for any of the outer rows or columns of the matrix (x, y) , and/or
- the mean value of B is higher than a fix pre-set value $T2$ of the outer rows or columns (x, y) .

15

A detection of arrhythmia is also performed and the existence thereof is considered if the lowest calculated variance for vectors A_{ij} increases a fix pre-set value $T3$ by the relation:

$$20 \quad \min_{i,j} \left[\frac{1}{(N-1)} \sum_{n=1}^N (A_{i,j,n} - \bar{A}_{i,j})^2 \right] > T3$$

wherein the vectors A_{ij} comprises the distances between the detected heart beats decided by applying a standard QRS-detector on every signal E_{ij} , and N is the

25 length of A_{ij} .

The selection algorithm is applied on one group representing one lead at a time. There are two alternatives for the selection of signals, wherein the preferred

30 alternative uses calculations based on the power spectra of the signals by the relation:

$$P_{i,j} = \frac{\int_{\omega_0}^{\omega_1} Y_{i,j}(\omega) d\omega}{\int_{\omega_1}^{\omega_2} Y_{i,j}(\omega) d\omega} \quad \text{where} \quad Y_{i,j}(\omega) = 2 \int_0^N R_{i,j}(\tau) \cos(\omega\tau) d\tau \quad \text{and}$$

$$R_{i,j}(\tau) = \frac{1}{N} \int_0^N E_{i,j}(t) \cdot E_{i,j}(t+\tau) dt$$

5 $\omega_0=10\text{Hz}$, $\omega_1=30\text{Hz}$, $\omega_2=fs/2$, and

fs is the sampling frequency and N the length of the signal. The signal having the highest value of $P_{i,j}$ is selected to represent the group if this value of $P_{i,j}$ increases a fix pre-set value $T4$; otherwise no signal is selected.

10

An alternative for the selection of a signal to represent a group is to use a relation based on matching:

$$M_{i,j}(x) = \sum_{n=x}^{x+n} ((E_{i,j}(n) - W_{i,j}(n-x))^2) \quad x: 0 \rightarrow (N-n)$$

15

$$W_{i,j}(x) = E_{i,j}(x) \quad x: 0 \rightarrow n$$

Where N is the length of $E_{i,j}$ and n is the length of $W_{i,j}$. $M_{i,j}$ should be lower than or be equal to a fix pre-set value $T5$. The signal having the lowest value of $M_{i,j}$ is selected to represent the group if this $M_{i,j}$ is lower than a fix pre-set value $T6$; otherwise no signal is selected.

20

Another purpose of the invention is to use the integral unit 10, 20, 30, 80 in a system for transferring the obtained signal information concerning the status of the heart of the patient to an external location, where medically skilled personal may analyse the information, and where the electrocardiogram can be displayed. Patients within the risk zone for a heart attack have hence the

25

30

possibility to perform a qualified measurement and to convey the information to an external location for a correct decision how to act. The requirements on such equipment are primarily that measurements are reliable and
5 are performed in real time, which the invention fulfils, so that the decision can be made upon the recently obtained values, preferably in relation to historical values and optimally with comments added from the patient.

A system for centralised management of medical data
10 is shown in US-4 974 607 comprising devices, e.g. a 3-electrode system for an electrocardiograph giving an indication of a heart disease in spite of few electrodes; a thermometer; a pulse meter; or other devices for measuring various bio-body information from a patient. The system
15 further includes a receiving section with a memory having stored values according to standard ranges or individual, permissible values to be compared with measured values; and a transmission section, which in case of obtaining not permissible values will transmit the obtained data via a
20 telephone line to a medical centre.

Since it is also desirable that the equipment is movable and compact and of course easy to operate by a person without any medical or technical knowledge, the integral unit 10, 20, 30, 80 according to the invention is
25 suitable in such a system for management of medical information, shown in FIG 12. The integral unit 10, 20, 30, 80 has pre-set conditions stored when delivered to the patient. The patient thus has to engage the first side 16 comprising the electrodes 11, 21, 31 of the integral unit
30 10, 20, 30, 80 with the torso of his/her body by the force of his/her hand as explained above. The communication unit 102 comprising a mobile terminal, e.g. a telephone having a transponder, will transfer the information data (the selected signals) in real time together with comments from
35 the patient in a coded format. Means for transferring the

information, e. g. by wireless transmission or GSM, GPRS and 3G or by another communication system, is provided. The information will first reach a security box 120 for decoding the data and verifying the identity of the patient, and to open a streamer of a database 121. The database 121 comprises several servers. Every patient that is recognised by the system has a space of his or her own on a server, where the newly received data will be stored together with earlier received data. As soon as new data arrives the address to a specific person in charge for this patient at a hospital or at another medical centre will be contacted by means of an additional communication unit 122, such as by telephone, Internet, Intranet, satellite chain, or by other well known technique. An identification check of this person will be performed before the newly received data is transferred to the person. A presentation 123 can now be made, such as displaying the signals as an electrocardiogram on a screen, and the medically skilled person can make a decision based on newly received patient data together with earlier values regarding the actions to be performed.

It should be understood that the described embodiments of the integral unit 10, 20, 30 are only examples of how the integral unit 10, 20, 30, 80 may be constructed, and that there are other possibilities within the scope of the invention for the construction thereof.

CLAIMS

1. An apparatus for detecting and measuring physiological signals comprising a sensor device having a
5 plurality of electrodes (11, 21, 31) isolated from each other to be non-invasively engaged with a torso of a human being, and signal processing means (90) connected to said plurality of electrodes (11, 21, 31), **characterized** in that
- 10 - the sensor device and the signal processing means (90) form an integral unit (10, 20, 30, 80) wherein a first side (16) of the integral unit (10, 20, 30, 80) comprises said plurality of electrodes (11, 21, 31) and a second side (17) opposite the first side (16) comprises the signal
15 processing means (90),
- said plurality of electrodes (11, 21, 31) are divided into groups (E1, E2, E3, E4, E5, E6, ER, EL, EN, EF) each including several electrodes (11, 21, 31) and each
20 representing a lead according to established standard for providing an electrocardiogram,
- said signal processing means comprises a memory and means for selecting (100) at detection of signals from the
25 electrodes (11, 21, 31) in each group (E1, E2, E3, E4, E5, E6, ER, EL, EN, EF) a single signal thereof according to pre-set values and conditions stored in the memory.
2. The apparatus according to claim 1, **characterized**
30 in that said integral unit (10, 20, 30, 80) forms a flat element to be kept engaged with the torso of the human being by manual force from a hand of said human being or another human being.

3. The apparatus according to claim 2, **characterized** in that said integral unit (10, 20, 30, 80) further comprises a power source (103).

5 4. The apparatus according to claim 3, **characterized** in that said integral unit (10, 20, 30, 80) comprises several individual layers (12, 13, 14, 15, 22, 23, 25, 32, 34, 35).

10 5. The apparatus according to claim 4, **characterized** in that the layers (12, 13, 14, 15, 22, 23, 25, 32, 34, 35) are made of flexible material.

15 6. The apparatus according to claim 5, **characterized** in that said plurality of electrodes (11, 21, 31) are arranged in a first layer (12, 22, 32) of said several individual layers (12, 13, 14, 15, 22, 23, 25, 32, 34, 35), made of an insulating material, with one end of said plurality of electrodes (11, 21, 31) protruding from said
20 first layer (12, 22, 32) forming said first side (16) of said integral unit (10, 20, 30, 80), and that the other end of said plurality of electrodes (11, 21, 31) are in communication with conductors in a second layer (13, 23, 34) of said several individual layers, which are connected
25 to said signal processing means (90) and said power source (103) in a third layer (15, 35) of said several individual layers (12, 13, 14, 15, 22, 23, 25, 32, 34, 35) forming said second side (17) of said integral unit (10, 20, 30).

30 7. The apparatus according to claim 6, **characterized** in that said electrodes (11, 31) are made of conductive polymer and are arranged transversally in said first layer (12, 22, 32) of said several layers (12, 13, 14, 15, 22, 23, 25, 32, 34, 35).

8. The apparatus according to claim 7, **characterized** in that the second layer (13) is a polymeric film provided with printed conductors.

5 9. The apparatus according to claim 7, **characterized** in that the second layer (13) is a flexible circuit board.

10 10. The apparatus according to claim 6, **characterized** in that the electrodes (21) are made of conductive textile material.

15 11. The apparatus according to claim 7, **characterized** in that a resilient fourth layer (14, 25) is provided between said second layer (13, 23, 34) and said third layer (15, 35) for distributing the force from the hand applied on said third layer (15, 35).

20 12. The apparatus according to claim 6 and 11, **characterized** in that said third layer (15, 35) is stiffer than said first (12, 22, 32), second (13, 23) and fourth (14, 25) layer, respectively, thus forming a protective shell of said integral unit (10, 20, 30, 80).

25 13. The apparatus according to any of the previous claims, **characterized** in that an output of said signal processing means (90) is connected to a communication unit (102) for transferring signals to a desired location external to said integral unit.

30 14. The apparatus according to claim 13, **characterized** in that said communication unit (102) comprises means for wireless transmission of signals to said location.

15. A signal processing method, wherein signal processing means (90) and a sensor device having a plurality of electrodes (11, 21, 31) are provided characterized by the steps of:

- 5 - providing an apparatus comprising said signal processing means (90), and said sensor device having said plurality of electrodes (11, 21, 31) forming an integral unit (10, 20, 30, 80), wherein the plurality of electrodes (11, 21, 31) are divided into groups (E1, E2, E3, E4, E5,
10 E6, ER, EL, EF, EN),
 - detecting and measuring one signal from each electrode (11, 21, 31) of said plurality of electrodes (11, 21, 31),
 - checking the position of the integral unit (10, 20,
15 30, 80) by comparing the measured intensities and the baseline variation of the signals with pre-set conditions,
 - comparing the value of each measured signal within each group (E1, E2, E3, E4, E5, E6, ER, EL, EF, EN) of signals with values stored in the memory, and
 - 20 - selecting one signal from each group (E1, E2, E3, E4, E5, E6, ER, EL, EF, EN) on the basis of a power spectra of the signal for forming an electrocardiogram.

16. The method according to claim 15, further
25 characterized by the step of:

- providing means (94, 100) for checking the position of the integral unit (10, 20, 30, 80).

17. A signal processing method, characterized by the
30 steps of:

- detecting and measuring one signal from each electrode (11, 21, 31) of a plurality of electrodes (11, 21, 31) divided into groups (E1, E2, E3, E4, E5, E6, ER, EL, EF, EN),

- checking the intensities and the baseline variation of the signals with pre-set conditions,
 - comparing the value of each measured signal within each group (E1, E2, E3, E4, E5, E6, ER, EL, EF, EN) of
5 signals with values stored in the memory, and
 - selecting one signal from each group (E1, E2, E3, E4, E5, E6, ER, EL, EF, EN) on the basis of a power spectra of the signal for forming an electrocardiogram.
- 10 18. A system for centralized management of medical data regarding physiological information comprising a sensor device having a plurality of electrodes (11, 21, 31), signal processing means (90) having means for wireless transmission, a communication unit (102), a security box
15 (120), a database (121) and means for presentation (123).

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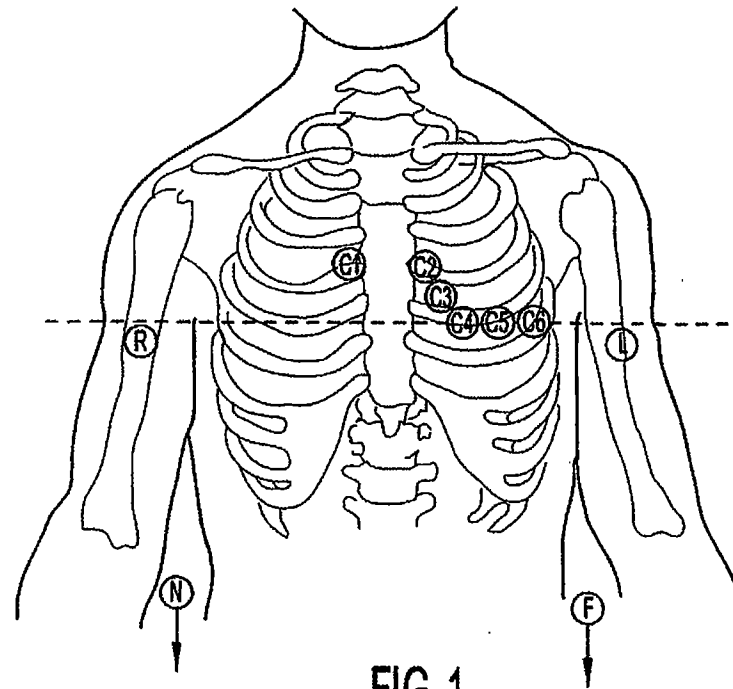


FIG 1

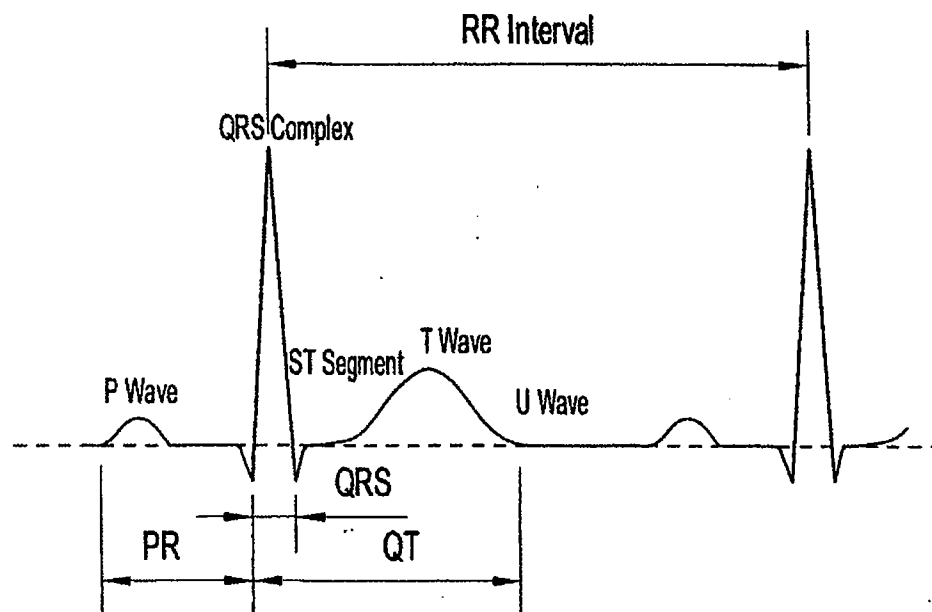


FIG 2

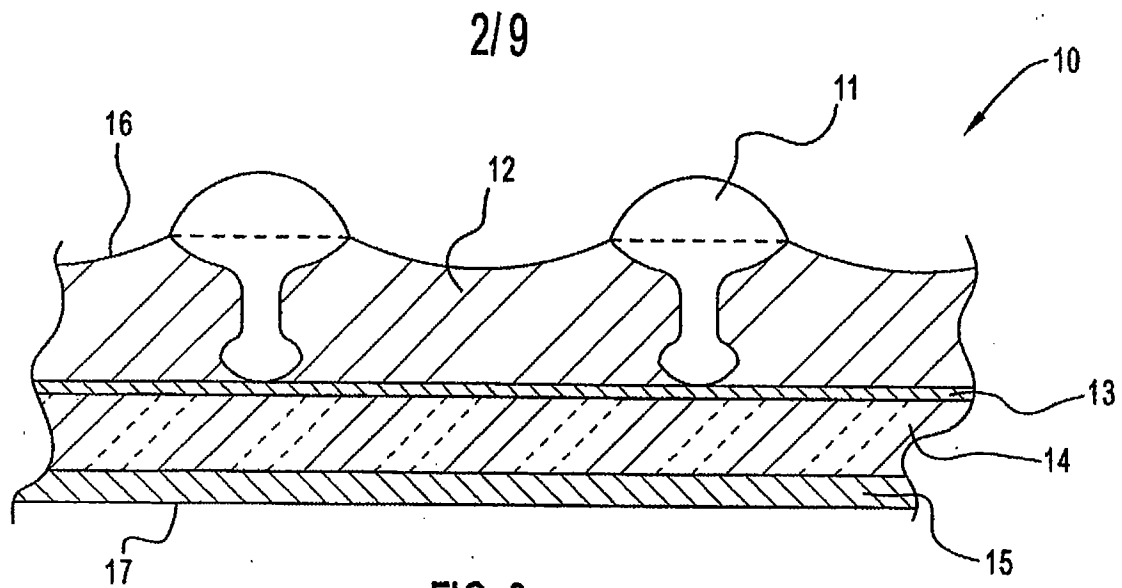


FIG 3

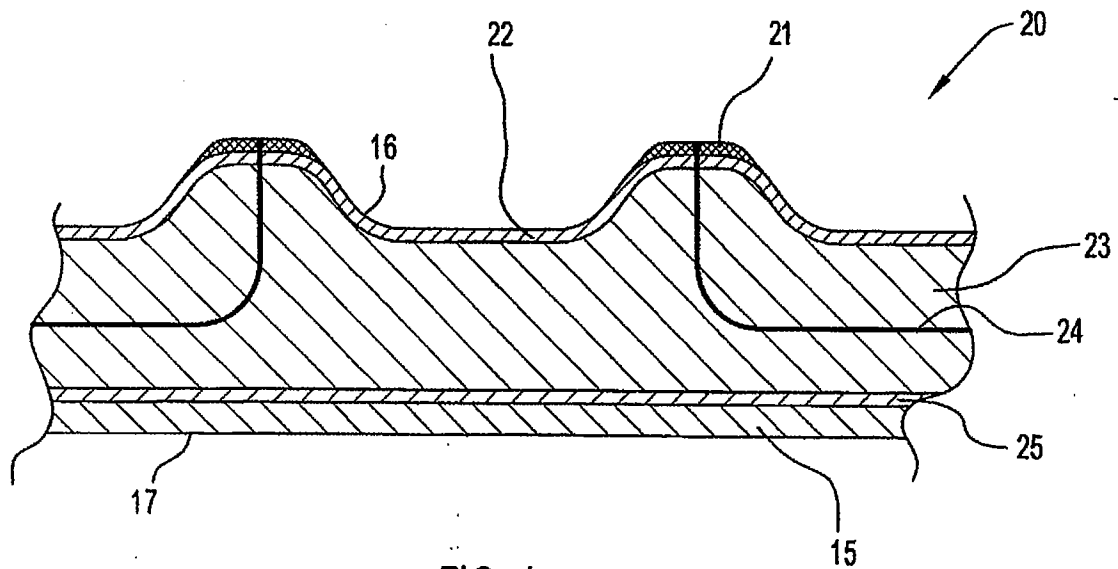


FIG 4

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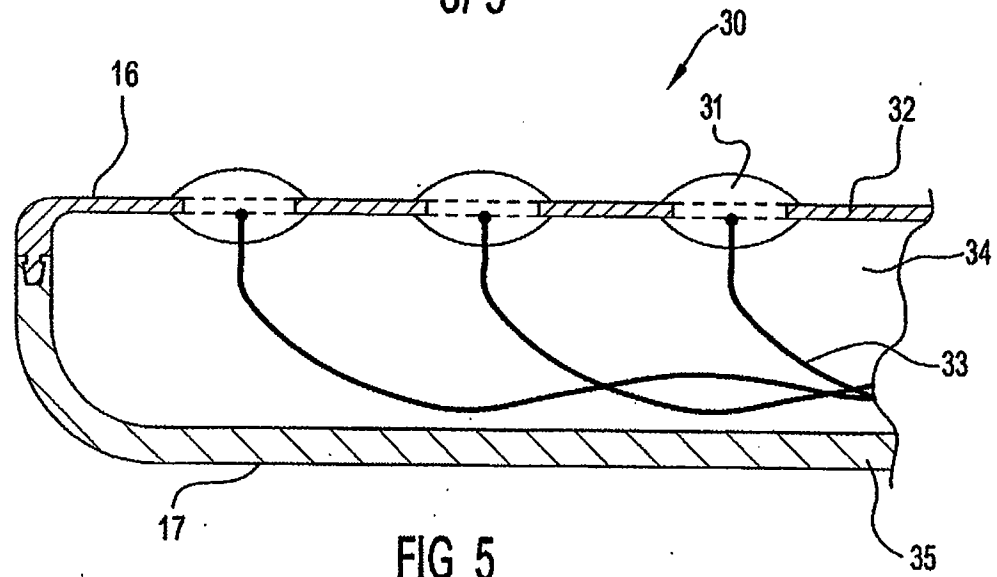


FIG 5

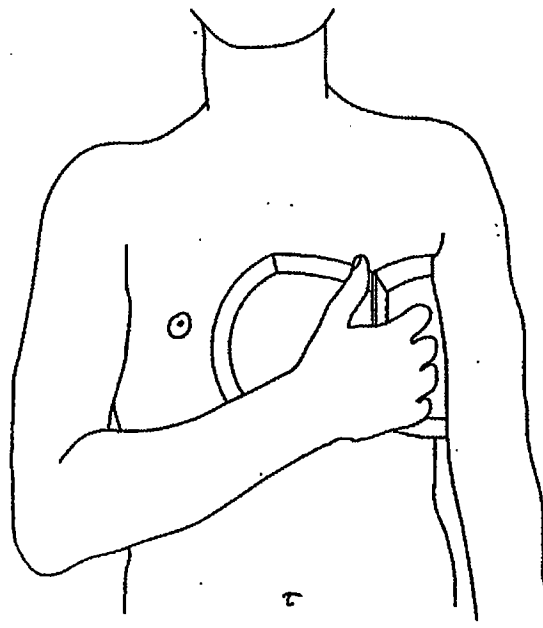


FIG 6

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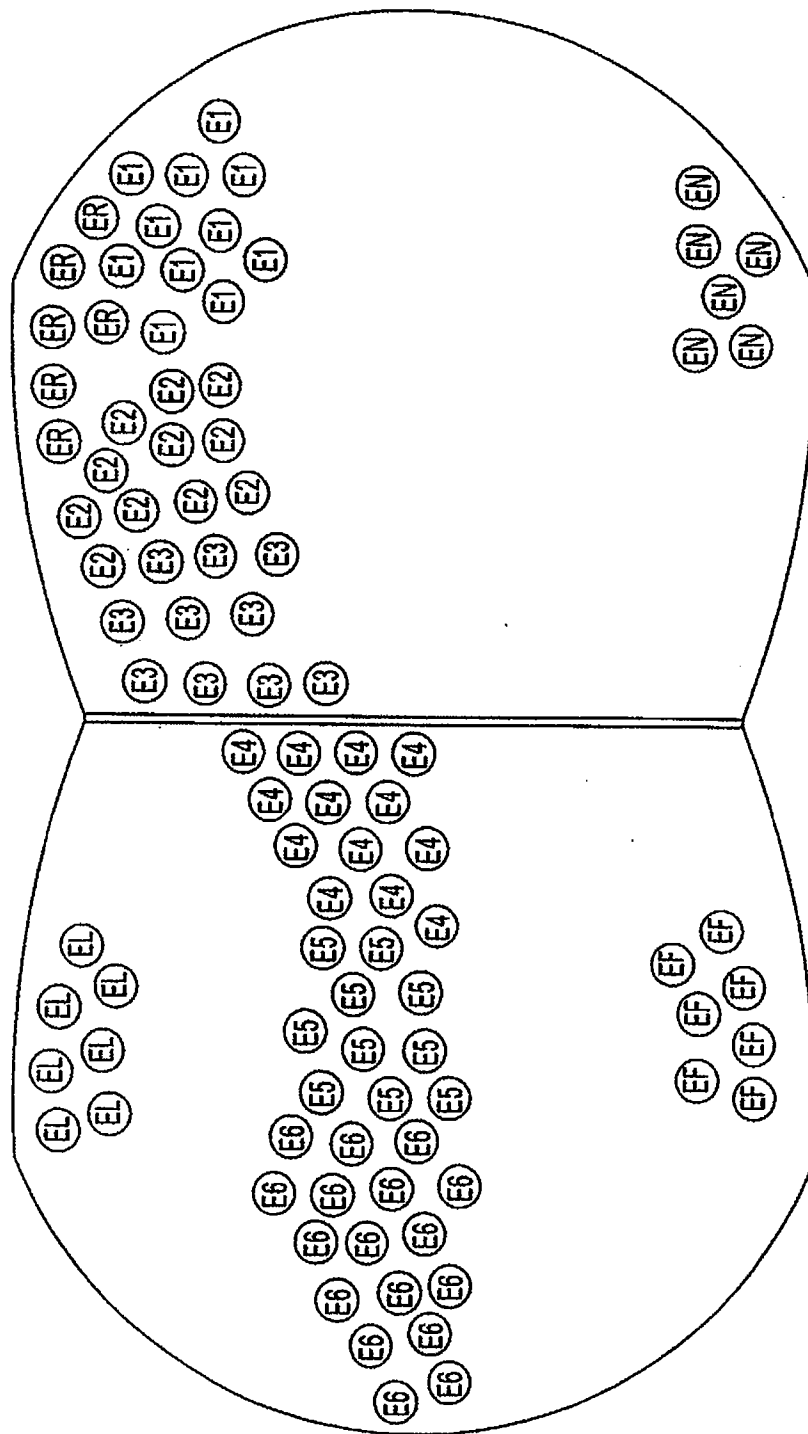
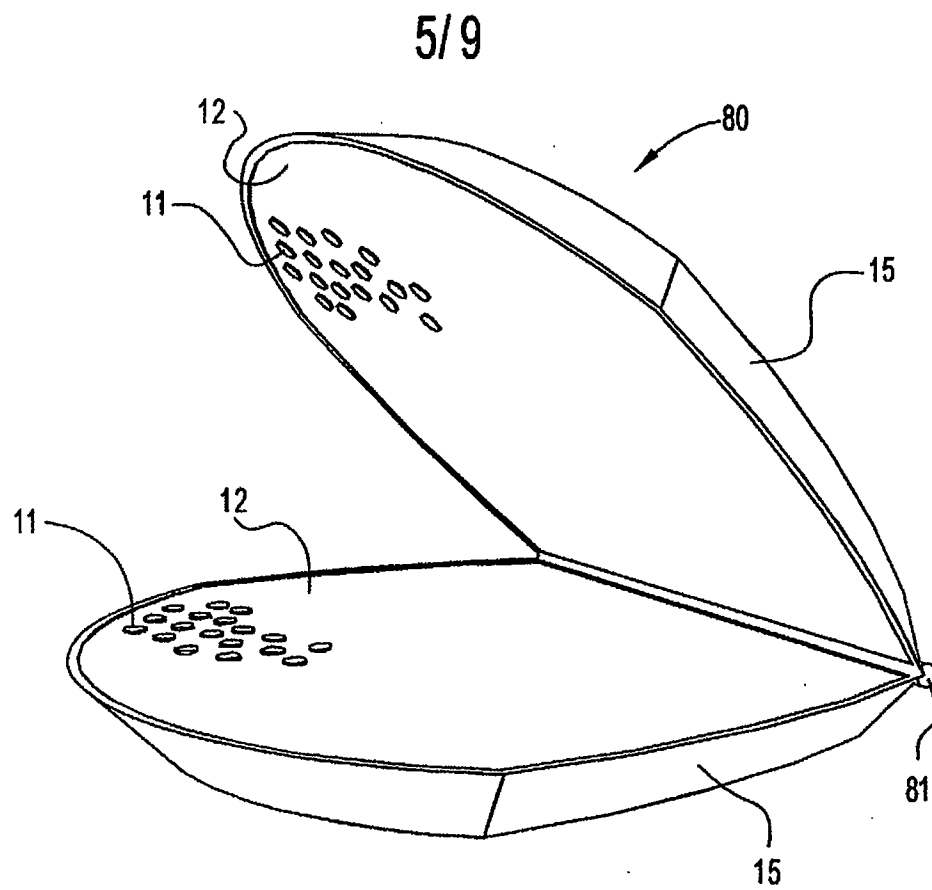


FIG 7



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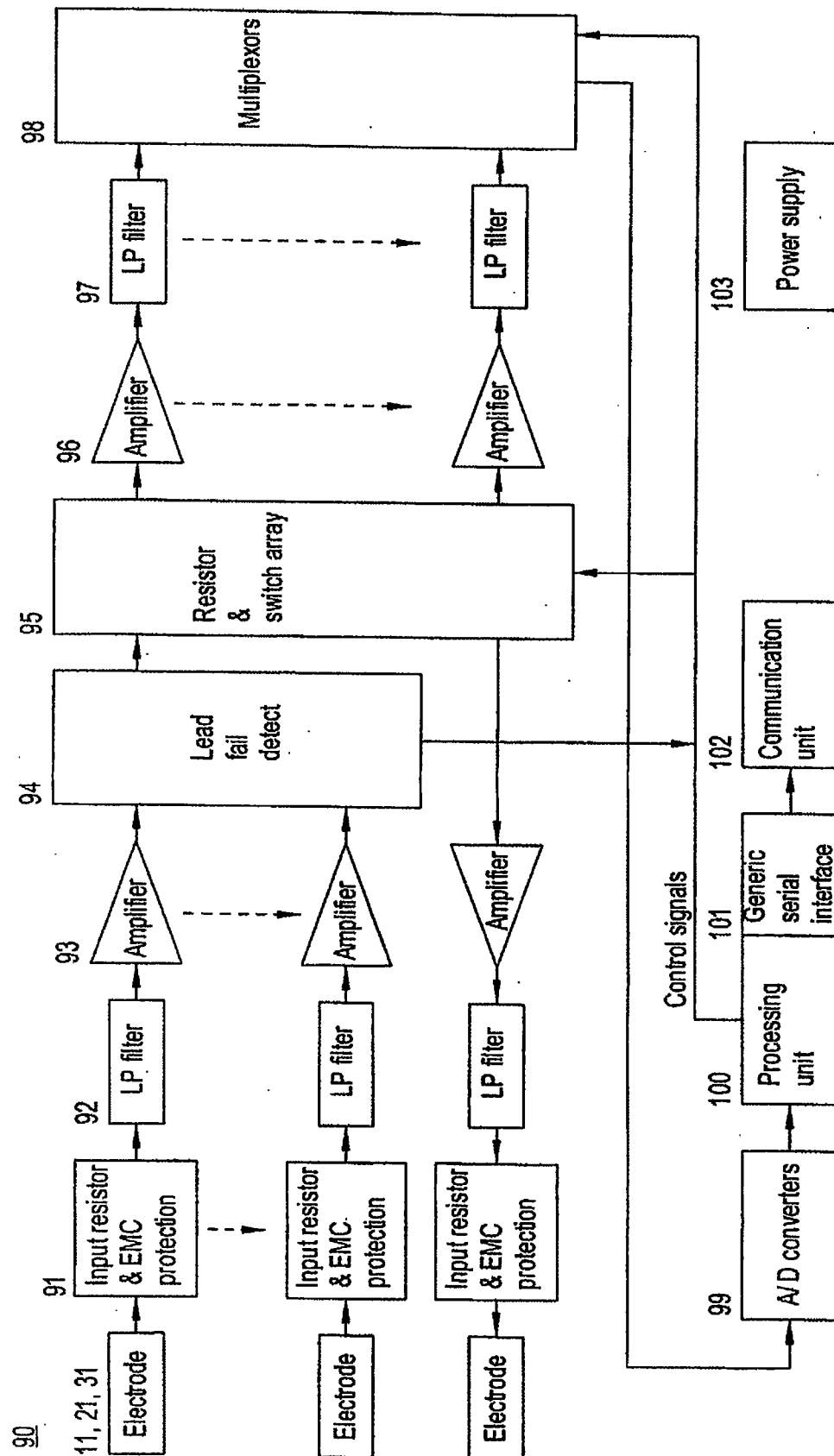


FIG 9

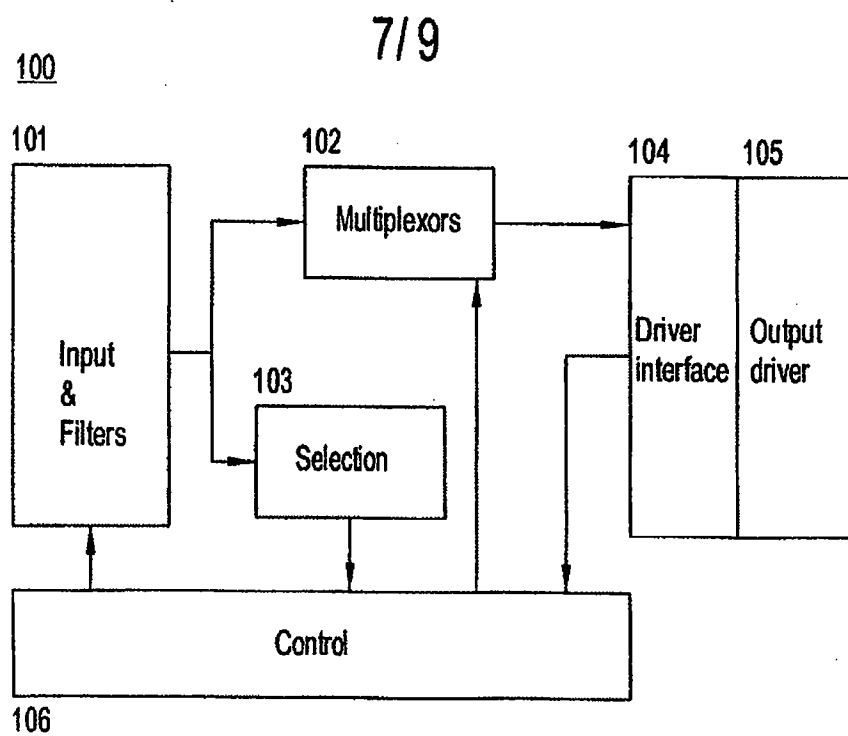


FIG 10

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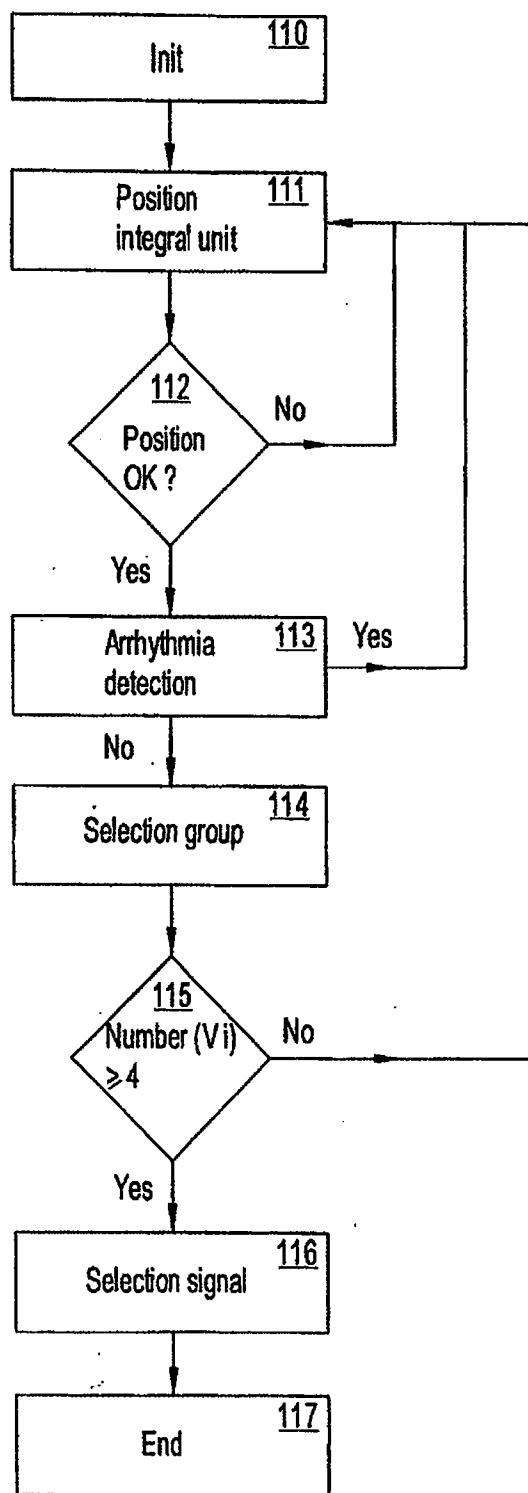


FIG 11

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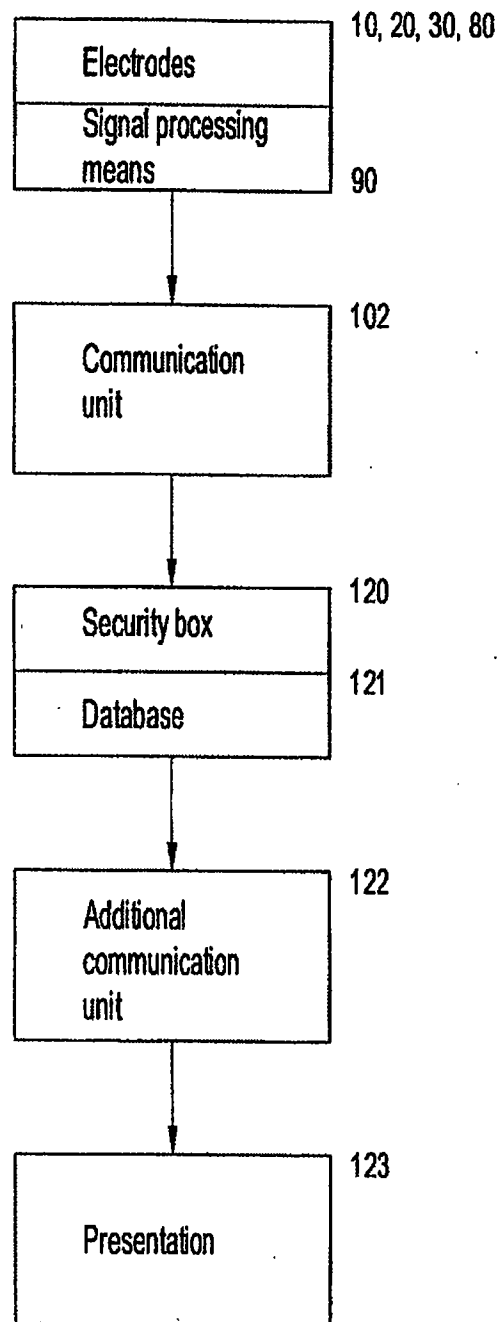


FIG 12

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/402

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,N0 classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5339823 A (H.E. REINHOLD, JR.), 23 August 1994 (23.08.94), figures 1,5,7, abstract --	1-17
Y	US 5184620 A (M.J. CUDAHY ET AL), 9 February 1993 (09.02.93), column 8, line 48 - column 9, line 10 --	1-17
A	WO 0113791 A1 (SHL TELEMEDICINE INTERNATIONAL LTD.), 1 March 2001 (01.03.01), page 6, line 10 - page 7, line 17, figures 1,2,5 -- -----	1-17

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 October 2002

Date of mailing of the international search report

04-10-2002

Name and mailing address of the ISA/

Swedish Patent Office

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See next page

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-17

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Invention 1: Independent claims 1, 15 and 17 relate to ECG equipment. The equipment includes multiple groups of electrodes and means for selecting one optimal electrode from each group of electrodes. Further, signal processing means are included.

Invention 2: Independent claim 18 relates to a system for central management of medical data, not necessarily ECG data. The system is provided with a number of electrodes, signal processing means, means for wireless transmission and a database.

The common technical features of the two inventions are that there are several electrodes and that there are signal processing means. Since these features are known to commonly appear in ECG systems, as indicated in the preamble of claim 1, the two inventions do not have a common special technical feature that avoids prior art. Thus, these inventions, a priori, lack unity of invention.

The search has been restricted to claims 1-17.

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/09/02

International application No.

PCT/SE 02/00981

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